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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/394,264	09/10/99	MORTON C	10286/008001

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1648	15

DATE MAILED: 06/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action	Application No. 09/394,264	Applicant(s) MORTON ET AL.	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

THE REPLY FILED 29 May 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *29 May 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search. (see NOTE below);

(b) ☐ they raise the issue of new matter. (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

4.☒ Applicant's reply has overcome the following rejection(s): *see continuation sheet*.

5.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

6.☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

7.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8.☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: *2, 29, 31 and 33*.

Claim(s) objected to: *3-7 and 18*.

Claim(s) rejected: *1,30, 32 and 34*.

Claim(s) withdrawn from consideration: *8-17 and 19-28*.

9. ☐ The proposed drawing correction filed on _____ a)☐has b)☐ has not been approved by the Examiner.

10.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

11.☐ Other:

The amendments filed 29 May 2001 have been entered but do not place the application in condition for allowance.

Applicant's arguments that the final rejection was erroneous have been fully considered but are not deemed persuasive. Applicant argues that the written description and enablement issues raised in the office action 19 April 2001 should have been raised in the office action 20 September 2000. This argument is not persuasive since the original claims were directed to nucleic acids selected from a group of five potential nucleic acid candidates. Art was applied to the originally claimed nucleic acids; the amended claims submitted in the response 23 March 2001 obviated the prior art rejection but necessitated the new written description and enablement rejections with the Final Rejection 19 April 2001. Therefore, the Final Rejection is deemed proper.

The rejection of claims 1, 2 and newly added claims 29-34 under 35 U.S.C. 102(a) as being anticipated by Robetson et al. (Genomics, December 1997) **is withdrawn** in view of the submission of the signed Katz declaration.

The rejection of claims 1, 2 and newly added claims 29-34 under 35 U.S.C. 102(a) or 102(b), **is withdrawn** in view of the submission of the signed Katz declaration.

The rejection of claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Robetson et al. (Genomics, December 1997) in view of the Pharmacia Catalog (1996) **is withdrawn** in view of the submission of the signed Katz declaration.

The rejection of claims 1, 30, 32 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is maintained** for reasons of record. Applicant's arguments have been fully considered but are not deemed fully persuasive. Applicant argues that more than one species (specifically two species) of COCH5B2 are disclosed and that the specification teaches which regions may tolerate variation. Applicant further argues that the biological activity is not based on mere homology modeling of the von Willibrand factor, but is based on the association of COL1A2, COL1A3, and DFNA9. The biological activities relied upon by applicant only indicate that these factors COL1A2, COL1A3, and DFNA9 are expressed in the same tissues as COCH5B2. Expression in the same tissue does not provide any information regarding the biological activities and does not give any evidence that these proteins actually interact with each other. The specification (see page 6, lines 18-25) lists the following activities for COCH5B2: (1) binding with extracellular matrix (2) modulate cell/extracellular matrix interaction (3) modulate cell-cell adhesion (4) bind glycoproteins and/or proteoglycans for clearing them (5) provide scaffolding with extracellular matrix (6) modulate inner ear secretory pathway. The listed activities are unsubstantiated in the instant specification or art (Robertson et al. Genomics 1994) which merely shows that COL1A2 and COL1A3 are expressed in the same tissue. Amending the claims to include the unsubstantiated limitation that the polypeptide must have at least one COCH5B2 activity does not obviate the rejection.

Claims 1, 30, 32 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention **is maintained** for reasons of record. Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that the biological activity is based on the association of COL1A2 and COL1A3. The biological activities relied upon by applicant only indicate that these factors COL1A2, COL1A3, and DFNA9 are expressed in the same tissues as COCH5B2. Expression in the same tissue does not provide any information regarding the biological activities and does not give any evidence that these proteins actually interact with each other. The specification (see page 6, lines 18-25) lists the following activities for COCH5B2: (1) binding with extracellular matrix (2) modulate cell/extracellular matrix interaction (3) modulate cell-cell adhesion (4) bind glycoproteins and/or proteoglycans for clearing them (5) provide scaffolding with extracellular matrix (6) modulate inner ear secretory pathway. The listed activities are unsubstantiated in the instant specification or art (Robertson et al. Genomics 1994) which merely shows that COL1A2 and COL1A3 are expressed in the same tissue, but tissue expression does not indicate that the proteins actually have an effect upon each other. Amending the claims to include the limitation that the polypeptide must have at least one COCH5B2 activity does not obviate the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER